Biotech Daily

Thursday April 22, 2021

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: OPTISCAN UP 17%; ALTERITY DOWN 17.5%**

*** ACTINOGEN PLANS 3 PHASE II COGNITION TRIALS FOR 2022**

*** CHIMERIC: 'NO CLTX-CAR-T DOSE-LIMITING TOXICITIES'**

*** PATRYS: PAT-DX1, PAT-DX3 'FAVORABLE' PK PROFILE**

*** IMPEDIMED: US FDA OKAYS SOZO HEART FAILURE INDEX**

*** OVENTUS: SLEEP METRICS TO PROMOTE O2VENT**

*** NOXOPHARM CLAIMS 'POSITIVE' INTERIM NOXCOVID RESULTS**

*** INCANNEX: FDA TALKS LEAD TO 3 IHL-675A APPLICATIONS**

*** INVEX: FDA MEETING FOR PRESENDIN FOR IIH**

*** HERAMED, JOONDALUP HERACARE PILOT PROGRAM**

*** MGC BUYS ISRAEL'S MEDICANL CRO FOR $6m IN SHARES**

*** MEDIBIO BEGINS 2nd MENTAL HEALTH APPLICATION TEST**

*** FIL TAKES 10% OF RESAPP**

MARKET REPORT

The Australian stock market was up 0.83 percent on Thursday April 22, 2021, with the ASX200 up 57.9 points to 7,055.4 points. Nineteen of the Biotech Daily Top 40 stocks were up, 14 fell and seven traded unchanged. All three Big Caps were up.

Optiscan was the best, up 5.5 cents or 17.2 percent to 37.5 cents, with one million shares traded. Impedimed improved 8.7 percent; Genetic Signatures climbed 7.3 percent; Actinogen and Amplia were up four percent or more; Nova Eye, Oncosil, Orthocell, Pro Medicus and Uscom were up three percent or more; Immutep, Nanosonics, Opthea and Resonance rose more than two percent; Clinuvel, Cochlear, CSL, Medical Developments, Polynovo and Resmed were up one percent or more; with Cyclopharm and Telix up by less than one percent.

Yesterday's 33.3 percent best, Alterity, led the falls, down 0.7 cents or 17.5 percent to 3.3 cents, with 98.8 million shares traded. Kazia lost 7.85 percent; Imugene and Osprey fell five percent or more; Proteomics and Starpharma were down more than three percent; Dimerix and Mesoblast shed two percent or more; Cynata, Neuren, Next Science and Pharmaxis were down more than one percent; with Avita and Volpara down by less than one percent.

ACTINOGEN MEDICAL

Actinogen's newly appointed chief executive officer Dr Steven Gourlay has wasted no time in reviewing Xanamem's data for cognition and planning three trials.

Dr Gourlay told Biotech Daily today that the company expected to have three separate phase II Australian trials running in 2022: for cognition in healthy elderly subjects; for Fragile X in boys aged 12 to 18 years; and the third an "undisclosed but exciting" trial for "cognition plus".

In 2014, Actinogen acquired UE2343 from Edinburgh University for Alzheimer's disease, appointing Pfizer's Dr Bill Ketelbey as its chief executive officer to run the program (BD: Aug 27, Dec 1, 15, 2014).

In 2017, the company began the 186-patient, phase II Xanadu trial of 10mg Xanamem for Alzheimer's disease, but in 2019 told the ASX that the trial "did not achieve statistical significance" (BD: Jan 22, 2017; May 7, 2019).

Actinogen said that despite missing efficacy endpoints the "results provide great encouragement to pursue higher dose and longer duration studies, consistent with ongoing Xanamem safety and target occupancy studies".

Also in 2019, Actinogen began the Xanahes trial of 20mg Xanamem or placebo for 12 weeks, followed by a second cohort receiving 30mg Xanamem or placebo daily to evaluate the safety of higher doses and cognitive efficacy (BD: May 29, 2019).

In October 2019, the company claimed success in the Xanahes trial of healthy elderly subjects, with a "statistically significant reduction in serum cortisol following treatment with Xanamem 20mg daily" ($p < 0.001$) (BD: Oct 1, 2019).

In February, Actinogen said it had been granted US Food and Drug Administration rare paediatric disease designation for Xanamem for Fragile X syndrome and might receive a priority review voucher if approved by the FDA, which could be used for different indications and could be sold, with average voucher sale prices of more than $US100 million ($A131.7 million) (BD: Feb 5, 2021).

Dr Ketelbey resigned on February 5 and Dr Gourlay was appointed chief executive officer on March 15, 2021.

Today, Dr Gourlay said that part 1 of the phase II Xanamia trial would enrol about 100 healthy elderly subjects for a dose-ranging study comparing 5mg and 10mg Xanamem with placebo to confirm cognition, including a digit substitution test.

Dr Gourlay said the extension of the previous study was expected to begin "mid-year and report early next year".

Dr Gourlay said that part 2 of the trial would investigate Xanamem for mild cognitive impairment in Alzheimer's patients, starting after part 1 concluded AND with results expected in 2023.

Dr Gourlay said that, subject to further discussions with the FDA, the second phase II trial of Xanamen would be in 30 to 40 boys aged 12 to 18 years with Fragile X syndrome.

He said that the company was aiming to begin the trial "this year and report in 2023".

Dr Gourlay said there were no approved drugs for Fragile X and the trial would include a mix of caregiver and clinician observations as well objective measures such as eye-tracking.

He said the phase II trial was hoped "to lead to a modest sized phase III trial in the orphan designation.

Dr Gourlay said the third trial was "undisclosed but exciting … and would start this year or early next year" with endpoints described as "cognition plus".

He said that all three trials were fully-funded with the cash currently held by the company.

Actinogen was up 0.2 cents or four percent to 5.2 cents with 23.4 million shares traded.

CHIMERIC THERAPEUTICS

Chimeric says the 28-day follow-up of the first cohort in its phase I trial of chlorotoxin chimeric antigen receptor T-cells (CLTX-Car-T) showed no “dose-limiting toxicities”.
Last month, Chimeric said it had dosed the first four-patient cohort in its up-to 36-patient, phase I study of CLXT-Car-T for glioblastoma (BD: Mar 18, 2021).
Today, the company said the first cohort received 44 million Car-T cells and the second dosing level of 88 million Car T-cells would be intra-tumoral or intra-cranial intra-ventricular.
Chimeric said the study was being conducted at the Duarte, California-based City of Hope to evaluate safety and the maximum tolerated dose CLTX-Car-T for patients with recurrent or progressive glioblastoma.
Chimeric fell one cent or 3.4 percent to 28.5 cents with 3.2 million shares traded.

PATRYS

Patrys says it has completed its pharmaco-kinetic study of its deoxymab antibodies PAT-DX1 and PAT-DX3 for cancer.
Patrys said the study in rats showed that both antibodies had a “favorable” pharmaco-kinetic profile with the differences in size of the PAT-DX1 antibody fragment and the PAT-DX3 full-sized immunoglobulin G (IgG) antibody potentially opening different clinical applications.
The company said PAT-DX1 was a “rapidly cleared from circulation” while PAT-DX3 “resided in circulation for a significantly longer period of time”.
Patrys said the study observed the antibodies to be “well-tolerated, with no body weight loss or visible clinical side effects”.
Patrys managing-director Dr James Campbell said that “the different [pharmaco-kinetic] profiles of PAT-DX1 and PAT-DX3 have opened up a greater range of partnering and development opportunities”.
Dr Campbell said he expected to begin the first clinical trials of PAT-DX1 by July 2022 and would build the pre-clinical dossier for PAT-DX3.
Patrys was unchanged at 2.7 cents with 3.3 million shares traded.

IMPEDIMED

Impedimed says the US Food and Drug Administration has cleared its Sozo device to include a heart failure index as a monitoring tool for heart failure patients.
Impedimed said its Sozo heart failure index (HF-Dex) analysis would provide an “objective” measure of fluid levels through a 30-second, non-invasive and “easy to administer” test.
Impedimed managing-director Richard Carreon said the company was “very pleased with this expanded clearance for Sozo that includes our heart failure index”,
“This is a major step forward in Sozo becoming the standard-of-care for the management of heart failure patients,” Mr Carreon said.
“The use of HF-Dex will provide clinicians with unparalleled insights into the extra-cellular fluid accumulation in heart failure patients that has not otherwise been readily available to them before,” Mr Carreon said.
Impedimed was up one cent or 8.7 percent to 12.5 cents with 5.35 million shares traded.

OVENTUS MEDICAL

Oventus says it has an agreement with Portland, Oregon-based Sleep Metrics for its virtual laboratory-inside-a-laboratory platform business model.
Oventus chief executive officer Dr Chris Hart previously told Biotech Daily that the laboratory-inside-a-laboratory "uses a scanner to measure the patient's mouth size for a custom-fit for the O2Vent" for sleep apnoea (BD: Jun 24, 2019).
Today, the company said Sleep Metrics provided at-home sleep studies and obstructive sleep apnoea treatment in Oregon and southern Washington, conducting about 100 in-home sleep studies and about 80 continuous positive airway pressure (CPAP) patients every month.
Oventus said Sleep Metrics would promote its sleep apnoea treatment platform O2vent Optima and 'Lab in Lab' business model as an alternative to patients who refuse or find continuous positive airway pressure therapy challenging, from next month.
Dr Hart said that "there were tremendous synergies with our [virtual laboratory inside a laboratory] model and Sleep Metrics' existing-at-home obstructive sleep apnoea testing", Oventus fell 1.5 cents or 7.3 percent to 19 cents.

NOXOPHARM

Noxopharm says interim results from the first 18-patients with moderate Covid-19 in its Veyonda Noxcovid trial show a "protective effect" against hyper-inflammation.
Noxopharm said the analysis involved a panel of biomarkers for inflammation, coagulation, sepsis and Covid-19.
The company said samples were collected on days one, three, seven and 14 and a range of biomarkers for Covid-19 did not rise in any of the 18 patients.
Noxopharm said it expected the biomarker data from the Veyonda 1800 mg dose cohort "within the next few weeks".
Noxopharm chief executive officer Dr Graham Kelly said Veyonda could block "the inflammation process in patients with moderate Covid-19 disease".
Noxopharm was up two cents or 3.2 percent to 65 cents with 1.7 million shares traded.

INCANNEX HEALTHCARE

Incannex says it had a "positive" pre-investigational new drug (IND) application meeting with the US Food and Drug Administration and will submit three INDs.
Incannex said it intended to expand its program to assess the potential of its cannabidiol and hydroxychloroquine combination drug IHL-675A as a multi-use pharmaceutical drug for lung inflammation, irritable bowel disease and rheumatoid arthritis.
The company said the marketing applications would use the FDA 505(b)(2) route and it would combine its acute respiratory distress syndrome (Ards) and sepsis associated Ards (Saards) with pulmonary neutrophilia, including chronic obstructive pulmonary disease, asthma, and bronchitis, development activities into a common project and application.
Incannex said that it would conduct a phase I trial to form part of three distinct development programs and applications for lung inflammation, irritable bowel disease (IBD) and rheumatoid arthritis.
The company said that a 505(b)(2) new drug application contained safety and effectiveness reports but allowed some of the required information, such as safety and efficacy information on the active ingredients, to originate from historical studies, resulting in an accelerated and less-costly route to approval, compared with a traditional 505(b)(1).
Incannex fell 1.5 cents or 5.2 percent to 27.5 cents with 14.3 million shares traded.

INVEX THERAPEUTICS

Invex says it has a meeting with the US Food and Drug Administration to discuss its phase III trial for Presendin for the treatment of idiopathic intracranial hypertension (IIH).
Invex said it was seeking guidance on the design, clinical endpoints, and statistical analysis methods for the Presendin (formerly Exenatide) trial.
The company said it expected the US Food and Drug Administration to provide the written only responses for its type C meeting by “mid-June 2021”.
Invex chairman Dr Jason Loveridge said that the trial sought to examine neurological measures including intracranial pressure and headache as clinical endpoints “hence the [FDA’s] Division of Neurology’s input will provide invaluable feedback”.
Invex fell one cent or 1.3 percent to 74.5 cents.

HERAMED

Heramed says it has a commercial agreement with Joondalup Health Campus for a pilot program of its Heracare pregnancy monitoring software.
Heramed said the agreement with Western Australia’s Joondalup Health Campus would provide 100 expectant mothers Heracare pregnancy monitoring software subscription for $50 a month each and the use of the Herabeat device for foetal heart rate monitoring in tele-health consultations.
The company said that after completion of the pilot program, both companies intended to begin a collaboration agreement for full deployment of the Heracare platform as a standard service at Joondalup Health Campus.
Heramed was up two cents or 16.7 percent to 14 cents with 3.3 million shares traded.

MGC PHARMACEUTICALS

MGC says it will acquire the Zichron Yaakov, Israel-based clinical research company Medicanl for $6 million in shares.
MGC said the share price would be based on the 10-day volume weighted average price calculated from settlement date, with 30 percent issued at settlement and the remaining 70 percent in instalments at four months, seven months, 10 months and 13 months from settlement.
The company said Medicanl would design, manage and run its clinical trials in accordance with US, EU and Israeli health regulations.
MGC said Medicanl currently had 11 clients and was working on 40 different projects and trials, and generated about $1 million in revenue in 2020 with a 25 percent profit margin.
The company said it had planned two phase I and phase II trials and one phase III trial planned in 2021 for its marijuana-based Cannepil, Cognicann and Cimetra.
MGC co-founder Roby Zomer said that “by acquiring Medicanl and bringing their services and expertise in-house, we not only cut significant costs from our forecasted clinical trial expenditure but also remove much of the red tape involved in the pre-clinical and clinical trial process.”
MGC was up 0.2 cents or 3.3 percent to 6.2 cents with 9.9 million shares traded.

MEDIBIO

Medibio says it has begun the second test of its consumer mental health application and is on-track for a commercial launch in October 2021.

In January, Medibio said it had begun testing the application, which aimed to detect and screen for mental health conditions by monitoring the users' overnight heart rate (BD: Jan 17, 2021).

Today, the company said the second test began on April 12 to assess the application's connectivity with wearable devices and its efficacy of undertaking the psychometric stress assessment on mobile phones and wearable devices.

The company said the biometric data collected would be used to refine its algorithms to produce a daily, individual-based stress result for sleep, activity and heart rate for an overall stress assessment.

Medibio was unchanged at 0.8 cents with 5.4 million shares traded.

RESAPP HEALTH

FIL Investment Management says it has increased its substantial shareholding in Resapp from 63,999,559 shares (8.44%) to 85,833,787 shares (9.99%).

Last week, Resapp said it had firm commitments to raise $5.5 million through a placement at 5.8 cents a share (BD: Apr 12, 2021).

Today the Hong Kong-based FIL said that between March 12 and April 19, 2021 it bought 25,897,402 shares in a placement at 5.8 cents a share and sold shares at prices ranging from 6.7 to 7.0 cents a share.

Resapp fell 0.1 cents or 1.8 percent to 5.4 cents with 5.2 million shares traded.